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## DEVICE FOR AN INHALER

### TECHNICAL AREA

The present invention relates to a device for a medical distributor,  
 5 which distributor comprises a drug delivery opening, compartment  
 containing medicament to be delivered, an energy system comprising  
 actuating means capable of delivering a dose of medicament from the  
 compartment and activating means capable of activating said  
 actuating means, whereupon activation of the device a force acting on  
 10 the activating means is transmitted to the actuating means, whereby  
 a dose of medicament is delivered through said drug delivery opening.

### TECHNICAL BACKGROUND

Many medical distribution products today have some sort of drug  
 15 container comprising a number of doses of medicament and a drug  
 delivery opening through which the medicament is delivered. For  
 example these comprise inhalers such as aerosol inhalers where the  
 medicament and propellant is contained in a canister or the like. The  
 canister comprises a hollow stem through which the medicament is  
 20 delivered when the stem is pressed into the canister. Other inhalers  
 have the medicament in powder form, where the powder is contained  
 in blisters or the like. When the medicament is to be delivered, the  
 blister is opened, either by tearing the blister open or by piercing it so  
 that an opening is created. With nebulisers, an ampoule or blister or  
 25 other container holding the medicament is pierced or slit open.

Other medical distribution products are injectors where the  
 medicament is contained in a syringe, which in turn is placed in a  
 casing, which injectors automatically or semi-automatically perform  
 30 different functions such as injecting the needle into the patient,

delivering the medicament from the syringe and retracting the needle or ejecting a needle protector.

For the drug to be delivered from these devices, they are provided  
5 with some kind of actuating means. These often comprise springs or  
the like which could be "energised" i.e. tensioned and held in that  
state until they are released. The actuating means could be energised  
either manually by a lever, sliding button or the like tensioning the  
actuating means or automatically whereby they are tensioned by  
10 moving components of the device. In order to be held in an energised  
state, the devices comprise a locking means capable of holding the  
actuating means in an energised state. Depending on device, the  
actuating means, when released by the locking means, depress a  
canister, puncture a blister or ampoule or push the plunger of a  
15 syringe, etc.

The devices further comprise some sort of activating means  
operationally attached to the actuating means and capable of  
releasing the locking means when the patient is to receive a dose of  
20 medicament. These actuating means could be purely manually  
operated, such as a button, a lever or a handle arranged on the outer  
surface of the device. The patient then presses or moves the  
activating means in order to release the locking means.

25 For many inhalers, the activating means is a flap or a vane that is  
arranged adjacent an air intake on the inhaler and substantially  
blocking the air intake when not activated. When a patient inhales  
through an inhalation opening, a pressure difference occurs over the  
vane or flap. This pressure difference causes the flap or vane to move  
30 and thereby open the air intake so that an inhalation air flow is  
created. This movement of the flap or vane releases the locking

means so that the actuating means is activated and a dose is delivered.

The spring means of the actuating means are often rather powerful.

- 5 For instance with aerosol driven inhalers the spring means have to be able to depress the canister so that a dose is delivered. This means that a stem of the canister has to be pushed into the canister against the spring force of the stem and against the friction caused by the seals around the stem.

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- For auto-injectors there could be several actuating means. Firstly the needle has to be pushed into the patient. Then the plunger is pressed into the syringe in order to deliver the medicament. After the drug is delivered, the needle is withdrawn either by retracting it into the  
15 auto-injector housing or by pushing forward a needle protection means.

- The fact that the force of the actuating means is relatively high and that it thus requires relatively high forces in order to hold or lock it in  
20 an energised state, at the same time as the forces for activating the actuating means need to be low, requires some form of transmission in order for the low activating force to be able to release the actuating force. It may be seen as one single energy system where a small input force provides a large output force.

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Because of this relation, quite a number of components are required, which components will affect the energy system due to for example friction of components, tolerances and spring characteristics, giving rise to variations in force required for releasing the actuating means.

- 30 Because it is one single interconnected system, the force for activating the activating means will thus also vary.

For most medical devices this is not acceptable because the activation should occur within a relatively narrow, well-defined force range. In order to cope with this, conventional techniques for these  
5 devices try to keep the number of components to a minimum and with high demands on tolerances in order to minimise the variations, in order to try to obtain predictable and repetitive conditions.

The strive to keep the number of component down and working with  
10 high tolerance requirements gives a rather costly device, by which it even so is difficult to manage all conditions.

One example is aerosol inhalers, where one, due to environmental considerations, is switching from canisters with CFC as propellant to  
15 HFA. HFA however requires much stronger seals whereby the force required to depress the canister may be substantially higher than for the CFC-canisters. With the same activating means, the variations will increase in the same degree. In order to cope with this, even higher demands on tolerances are required.

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The above mentioned problems are also very much pronounced with some devices, such as multiple automatic functions acting in sequence of each other, with long and/or multiple energy systems where it is important that the forces required for triggering the  
25 different actuating means are certain to be provided without over-dimensioning the activating means. Otherwise, either it is not certain that the different functions are able to sequentially trigger each other or the device will be unnecessarily bulky and difficult to use.

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## BRIEF DESCRIPTION OF THE INVENTION

The aim of the present invention is to remedy the above mentioned problems with known medical delivering devices, and to obtain a reliable, predictable and repeatable activation of the device for  
5 delivering medicament.

This aim is solved by the present invention characterised by claim 1.

The benefit of the present invention is that repeatable and predictable  
10 handling characteristics, like for example dose-to-dose equivalence, is obtained without the need for very fine, and thus costly, tolerance demands on the components.

With the present invention, the dimensioning of the force  
15 requirements is facilitated because the energy system is divided in two distinct parts, wherein the parts, when the device is non-activated, are in no physical contact with each other. The part comprising the actuating means and transmission is designed so that the actuating means may be released with reasonable demands on  
20 design, tolerances and the like, thus allowing a certain variation in force requirements. The other part of the energy system is designed and dimensioned such that it is activated at a certain predetermined and repeatable force level, and that the force available always is above the force range required for releasing the actuating means.

25 Because of the division, it is not necessary to take care of the variations through the entire system, but instead merely have to calibrate the activating part of the system. Because this part mostly contains rather few components, it is necessary to design and  
30 calibrate only the activating means and the release means so that the activating means is activated at a predetermined force.

When designing this part it is also only necessary to take into account the range within which the forces required for releasing the actuating means will vary and to ensure that the force available for releasing the actuating means is substantially above this area. In this way it is ensured that the device will be activated at a certain predetermined external force level, and that the activation ensures a release of the actuating means.

These and other aspects of, and advantages with, the present invention will become apparent from the following detailed description of non-limiting embodiments and from the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In the detailed description of the invention, reference will be made to the accompanying drawings, of which

Fig. 1 shows as an example of the present invention a side view in cross-section of an inhaler comprising the present invention, and Fig. 2 shows a detailed view of a transmission and locking means comprised in the invention, Fig. 3 shows a cross-sectional view taken along line III-III of Fig. 2.

#### DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows an example of an inhaler comprising the present invention. The inhaler 10 shown is intended for aerosol-driven medicament contained in a canister 12 arranged inside the housing 14 of the inhaler. A stem 16 of the canister is seated in a nozzle 18

provided with an outlet directed towards an inhalation mouthpiece 20.

The inhaler is further provided with breath- activating means, which  
5 comprises a flap or vane 22 pivotably arranged adjacent an air intake 24 and substantially covering the intake when non-activated. The flap or vane is arranged with a protrusion 26 adjacent its pivoting point 28. A release means is arranged to the activating means,  
10 comprising an arm 30 which is arranged with a hook 32 at its upper end, which hook grips a ledge 34, in turn arranged close to the protrusion. A compression spring 36 is arranged between the arm and the housing of the inhaler. The arm extends downward into a transmission and locking means 48.

15 A pressure arm 44 is arranged in contact with the top of the canister as seen in the figure and pivotable around a pivoting point 46 fixed to the housing.

The transmission and locking means 48, Figs. 2 and 3, comprises a  
20 first pivoting locking member 50, pivotable around an axis 52, which axis is fixedly attached to a stationary plate 53, partly taken away in Fig. 2 for clarity. The locking means is arranged with a surface 54 inclined with respect to a vertical axis as seen in Fig. 2. The lower end of the arm 30 is arranged with a mating inclined surface 56. The  
25 locking member is provided with an upwards facing ledge 58, on which ledge a first transmission member 60, pivotable around an axis 61, rests with a recess 62, thus holding the first transmission member in a substantially horizontal position. The axis 61 is also fixedly attached to the plate 53. A second transmission member 64,  
30 arranged pivotably around an axis 66 in a vertical direction rests with a lower end on the second transmission member. The second



transmission member is arranged with an arm 67 whose outer end is bent inwards in Fig. 2.

5 The upward facing surface 69 of the arm mates with a ledge arranged in a groove 71 of a movable plate 68. The shaft 66 of the second transmission member is also attached to the plate 53. A shuttle 76 is attached to the movable plate 68 via attachments 75. The lower end of the movable plate 68 is arranged with a ledge 70. Between this ledge 70 and a ledge 72 of the stationary plate 53 are arranged two  
10 compression springs 74. An arm 76 is attached to the shuttle 68. At the upper end of the arm 76 a hook 78 is arranged. The hook grips the free end of the pressure arm 44. The transmission and locking means also comprises suitable guide means for the different components, not shown.

15 The function is as follows. When a patient inhales through the mouthpiece 20, a pressure difference is created between the interior of the inhaler and the outside, and thus a pressure difference over the flap or vane 22. The pressure difference causes the flap or vane to  
20 pivot around its pivoting point 28. The pivoting movement causes the protrusion 26 to push the hook 32 of the arm 30 off the ledge 34 whereby it is forced downwards by the compression spring 36. The gap between the arm 30 and the locking member 50 provides an acceleration of the arm and thus a certain dynamical force. This force  
25 provides an additional feature and advantage in designing the system and the requirements for releasing the locking member.

The downward movement of the arm 30 of the release means, due to the spring 36, causes it to come in contact with its inclined surface  
30 56 against the inclined surface 54 of the locking member 50. The movement and the inclined surfaces causes the locking member to pivot clockwise in Fig. 2 whereby the ledge 58 of the locking member

is pushed out of contact with the recess 62 of the first transmission member 60. The first transmission member is thereby free to turn downwards, whereby the arm 67 of the second transmission member 64 is moved out of contact with the recess of the groove 71. This frees  
5 the movable plate 68, which is pushed downwards due to the force of the compression springs 74, whereby the shuttle 76 is also moved downwards due to being attached to the movable plate 68 via the attachments 75. The force of the compression springs is transmitted to the canister 12 via the pressure arm 44 and the canister is  
10 depressed.

As can be seen in Fig. 2, the connection between on the one hand the flap 22 and arm 30, the activating means, and on the other hand the locking and transmission means 48, transmitting the movement and  
15 actuating the delivery of the dose, the so called actuating means, is broken in that there is a gap between the arm 30 and the locking member 50. It is thus much easier to design and balance the activating means so that it is activated due to a predetermined pressure difference over the flap, and to design the compression  
20 spring 36 so that the force by the arm always is above a certain force required to trigger the rest of the system.

In designing the system it is possible to take care of the differences in the properties of all components of the transmission and actuating  
25 means in order to have a reliable, predictable and repeatable activation of the inhaler.

In respect of the transmission described above, there could be more or fewer transmission members present depending on the forces  
30 available for triggering or unlocking the device and/or forces to be released. In this respect the transmission may also be of any

mechanism capable of transferring a movement and capable of enabling a low force to release a high force.

Even though the present invention has been described in connection  
5 with an aerosol inhaler, it is to be understood that it is equally applicable to other types of inhalers such as powder and nebulisers, as well as for nasal inhalers.

Several devices of the present invention may be used in the same  
10 medical distributor in sequence, dependent, or independent, of each other. With dependent is meant that one component is moved to an end position and thereby triggers a subsequent component. With independent is meant that one component is moved to an end position. The subsequent triggering is then performed by external  
15 activation.

For example in the above example, a return means could also be provided with the same function as the above described device. This could comprise a second locking and transmission means replacing  
20 the attachments 75 between the movable plate and the shuttle 76. It comprises a further arm, which, upon termination of inhalation, is released by the flap or vane, whereby it moves the second locking means out of locking position. This causes the shuttle 76 to be released from the movable plate 68, whereby the canister is returned  
25 to its non-depressed state by the spring arranged in the canister. Return means arranged to the movable plate 68 will push it upwards to the initial position, which for example may be done manually by shutting a hygiene lid or pushing a button.

30 As for injectors of the above described type, several devices according to the present invention may also be used in one injector. For instance one may be associated with the triggering of needle

penetration, which is often done by pushing the syringe forward in the housing of the injector. When the syringe is in the forward position, this triggers the emptying of the syringe. This is done by springs pushing the plunger into the syringe. When the plunger has  
5 reached the dose end position or bottom and the dose is delivered, this triggers a needle retraction or a needle protection to be pushed forward. There could thus be a series of components or transmissions acting in sequence, where each sequence could make use of the "broken connection" according to the invention. With the present  
10 invention there is thus easier to take into account and deal with variations in the characteristics of the components in the chain when calculating the forces required for the reliable function of the device.

In the description both force and energy have been used in describing  
15 the present invention. It is to be understood that are equally applicable. For example releasing the locking means, a certain force may be applied to the locking means in order to move it out of locking position. In the same context, a certain energy may also applied, which for example may comprise the dynamical energy obtained by  
20 the moving release means.

It is to be understood that the embodiments described above and shown in the drawings are non-limiting examples of the present invention and that it is defined by the scope of protection of the  
25 patent claims.

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## PATENT CLAIMS

1. Device for a medical distributor, which distributor comprises a drug delivery opening (20), compartment (12) containing medicament to be delivered, an energy system comprising actuating means (44, 74) capable of delivering a dose of medicament from the compartment and activating means (22, 26, 30, 36) capable of activating said actuating means, whereupon activation of the device a force/energy acting on the activating means is transmitted to the actuating means, whereby a dose of medicament is delivered through said drug delivery opening, characterised in that said energy system is divided in at least a first and a second energy system, the first energy system comprising said activating (22, 26) means and a release means (30, 36), said second energy system comprising said actuating means (44, 74) and a locking means (50, 60, 64, 68) arranged to the actuating means and capable of locking said actuating means in an energised state, wherein the systems, when the device is non-activated, are in no physical contact with each other, and wherein, upon activation of the activating means, the release means is moved into contact with, and moves, the locking means out of a locking position.
2. Device according to claim 1, characterised in that the activating means and release means are designed and adapted such that the force/energy provided by the first energy system upon activation is substantially higher than the force/energy required for releasing the second energy system.
3. Device according to any of the preceding claims, characterised in that the second energy system comprises a transmission, by which the force/energy required for releasing said

locking means is substantially less than the forces/energy required for holding said actuating means in an energised state.

4. Device according to any of the preceding claims,  
5 characterised in that the force/energy available from said first energy system is adapted such that it is substantially above the variations in force/energy requirements for activating the second energy system.

5. Device according to any of the preceding claims,  
10 characterised in that said first energy system is calibrated such that the activating means is activated at a predetermined threshold.

6. Device according to any of the preceding claims,  
characterised in that it is arranged in an inhaler, and that the  
15 activating means is arranged and adapted such that it is activated upon inhalation.

7. Device according to claim 6, characterised in that the  
activating means comprises a flap or vane arranged in said inhaler  
20 adjacent an air intake of said inhaler.

8. Device according to any of the preceding claims 1-5,  
characterised in that it is arranged in a medical injection device, and  
is arranged and adapted such that the activating means comprises a  
25 user-operated means, whereby, upon operation, the release means moves the locking means out of a locking position.

9. Medical distributor for distributing medicament to a  
patient comprising at least one device according to claim 1,  
30 characterised in that there are arranged several devices acting in sequence of each other, dependent or independent of each other.

10. Medical distributor according to claim 9, characterised in that the activating means of one device is activated upon start of inhalation and in that the activating means of a second device is activated upon termination of inalation.

5

11. Inhaler comprising a device according to claim 1.

12. Medical injector comprising a device according to claim 1.

APV00-03-06

**ABSTRACT**

The present invention relates to a device for a medical distributor, which distributor comprises a drug delivery opening (20), compartment (12) containing medicament to be delivered, an energy  
5 system comprising actuating means (44, 74) capable of delivering a dose of medicament from the compartment and activating means (22, 26, 30, 36) capable of activating said actuating means, whereupon activation of the device a force/energy acting on the activating means is transmitted to the actuating means, whereby a dose of medicament  
10 is delivered through said drug delivery opening. The invention is characterised in that said energy system is divided in at least a first and a second energy system, the first energy system comprising said activating (22, 26) means and a release means (30, 36), said second energy system comprising said actuating means (44, 74) and a  
15 locking means (50, 60, 64, 68) arranged to the actuating means and capable of locking said actuating means in an energised state, wherein the systems, when the device is non-activated, are in no physical contact with each other, and wherein, upon activation of the activating means, the release means is moved into contact with, and  
20 moves, the locking means out of a locking position.

(Fig. 2)

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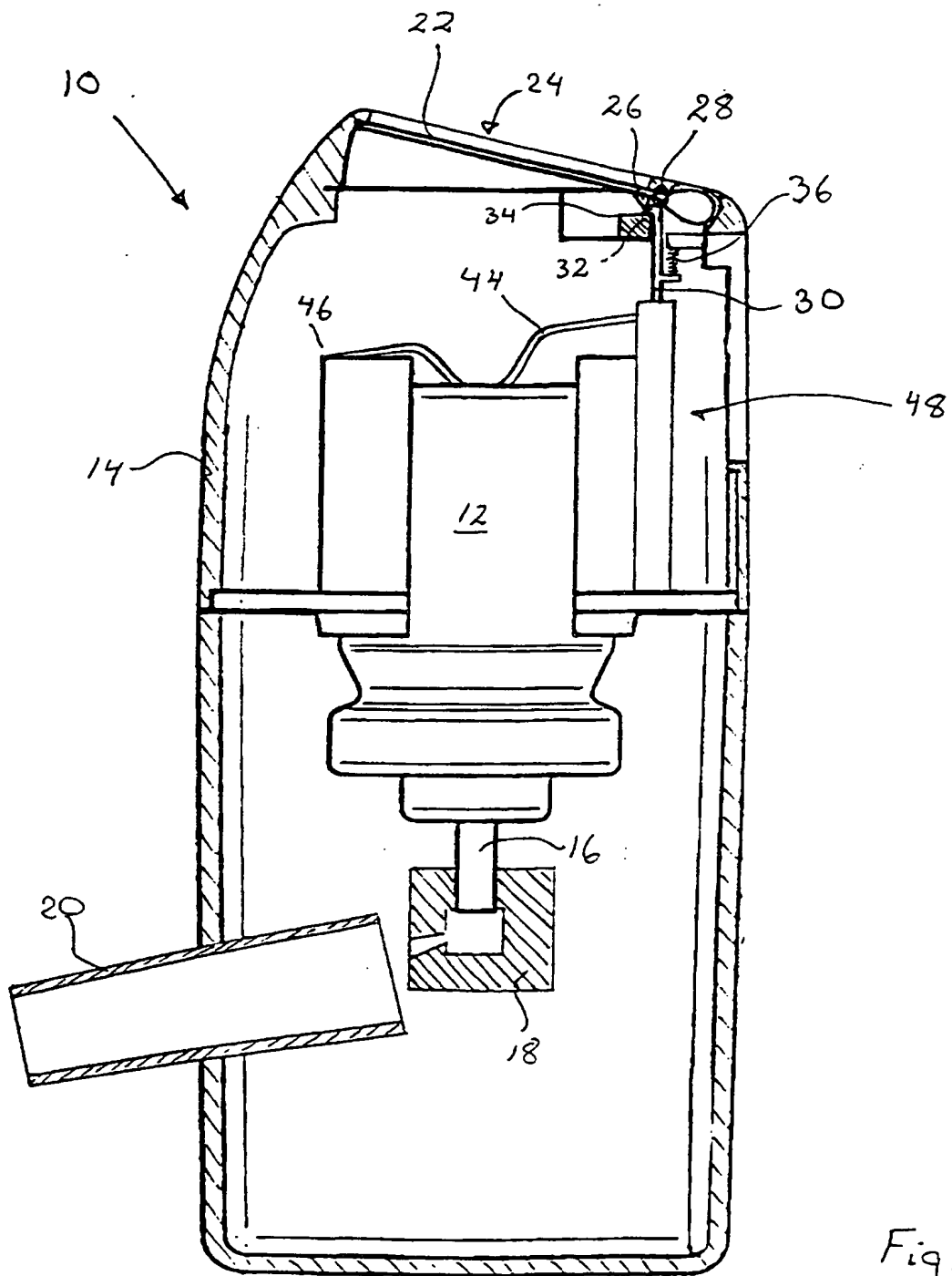


Fig. 1

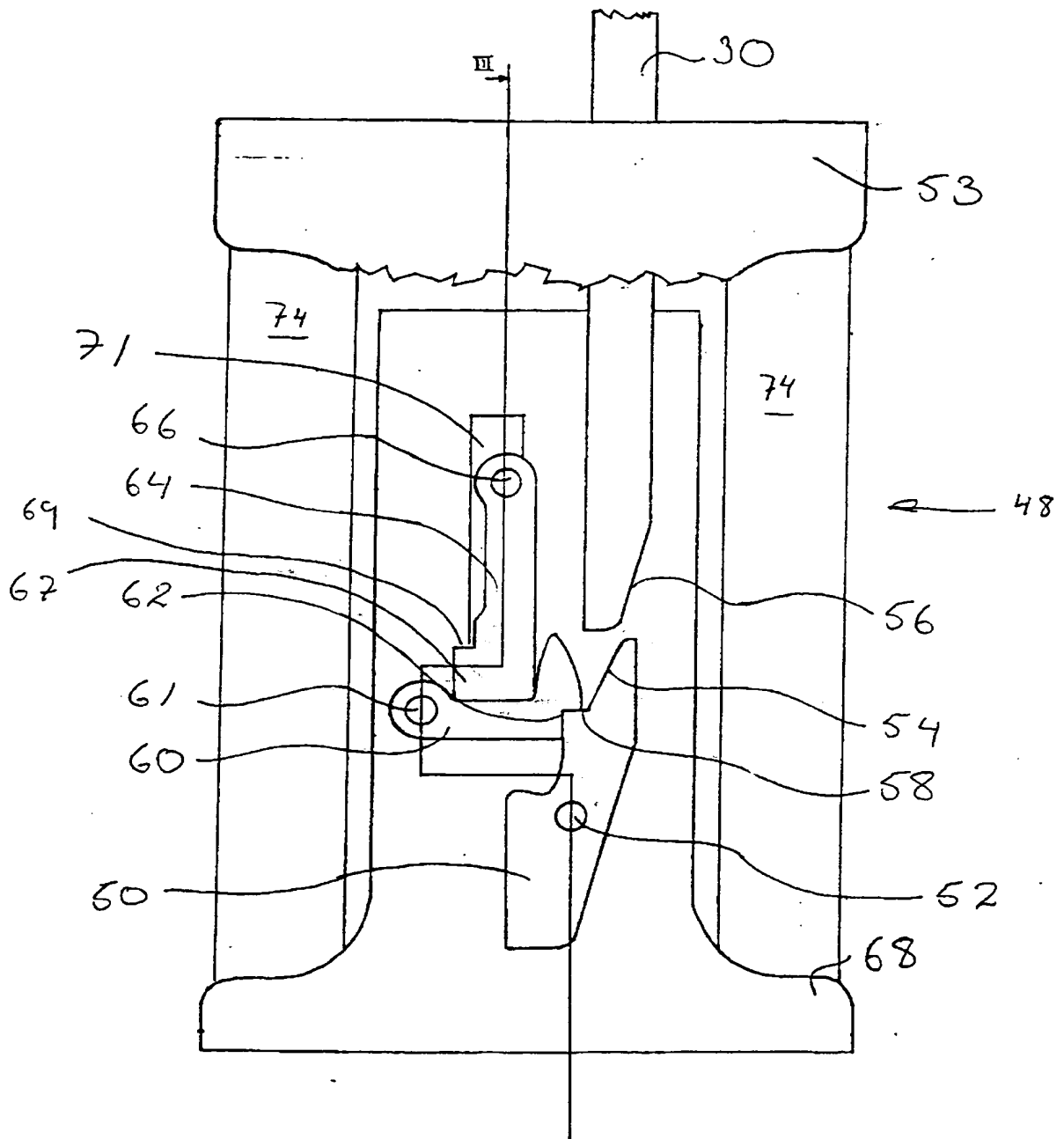
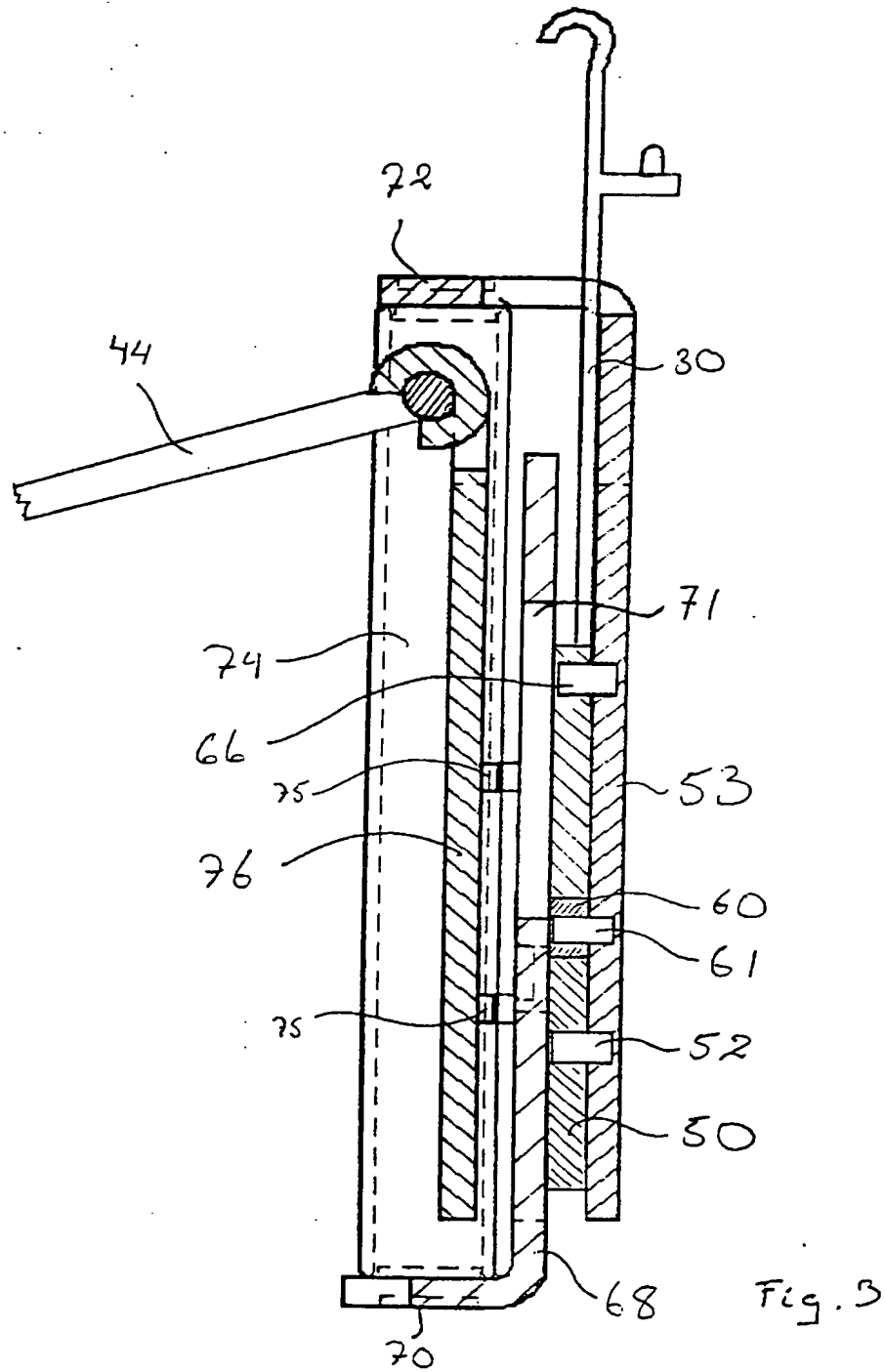


Fig. 2



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